REMARKS

REJECTIONS UNDER 35 USC §112

The examiner has rejected claims 55-99 under the first paragraph of 35 USC §112 for lack of adequate written description. Applicants have amended these claims to recite DNA constructs containing the promoter of the *B. vulgaris* V-ATPase subunit c in isoform 2 together with a heterologous gene. Applicants maintain that gene orthologs have strong sequence homology and should possess the same function and expression patterns, and make the amendment solely to further the present prosecution.

The examiner has rejected claims 55 and 62 under the second paragraph of §112 for lack of definiteness in use of the term "functional equivalent." Applicants introduce new claim 100 herein, which is drawn to DNA constructs containing functional equivalents of the *B. vulgaris* promoter at issue, together with heterologous genes. Claims 55 and 62 no longer recite this language. In creating this new independent claim, applicants submit that the referant of "functional equivalent" is now clear, and further submit that the definition of this term is also clear to one of ordinary skill in the art.

The examiner further rejects claims 55, 61, and 74 as indefinite in their use of the word "gene," stating that "the definition of gene given by one possessing the ordinary level of skill in the art would not exclude promoter sequences, noncoding

sequences and termination sequences" (advisory action, p.4). Applicants append hereto an excerpt from the Oxford Dictionary of Biotechnology which shows the entry for "gene" in that dictionary. In classical genetics, "gene" referred to a particular phenotypic characteristic, and was defined in terms of mutation or recombination rates. Under the central dogma of protein synthesis, "the 'one gene-one enzyme' hypothesis, ... a gene consisted of DNA that coded for a protein that performed the functions associated with the phenotypic expression of the gene." That definition has been modified in current molecular genetics in part to reflect the presence of regulatory sequences *associated with* genomic DNA.

As this entry demonstrates, genes are stretches of DNA that code for proteins. The genes may *contain* regulatory sequences, and the coded-for proteins themselves may serve regulatory functions with regard to other genes, yet the term "gene" is necessarily correlated with an associated protein. "Promoter sequences, noncoding sequences and termination sequences" are simply not genes (advisory action, p.4). Applicants submit that the definition of the word "gene" is sufficiently definite to one of skill in the art.

The examiner rejects claim 59 as indefinite, stating that "the manner in which the first and second promoters are regulated cannot be discerned from the claim" (*id.*). Claim 59 depends from claim 55, which recites a DNA construct comprising the specified promoter and a heterologous gene. The specification indicates that the claimed promoters are regulated at least in part by subjection to biotic or abiotic stress.

In contrast, the commonly-used 35s CaMV promoter, for example, does not respond to these stresses, but its routine use indicates that one of skill in the art could readily ascertain to what it *does* respond (*see, e.g.*, p.12:31-33, and p.13:1-13). Some promoters may respond both to biotic and abiotic stresses in the manner of the presently claimed promoters, and additionally respond to other triggers.

The language of claim 59 is therefore straightforward and definite. The claimed DNA construct comprises the specified V-ATPase promoter, regulated by biotic or abiotic stress, the heterologous gene, and a second promoter "which can be regulated in a different manner." Applicants submit that this is sufficiently definite for one of ordinary skill in the art.

The examiner further rejects claim 61 as indefinite. Applicants respectfully direct the examiner's attention to page 6 of the specification, where suitable resistance-mediating genes and other genes of interest are exemplified. Within the present art, the scope of coverage would be readily apparent to one of skill therein, given the disclosure set forward in the specification. Applicants are uncertain how selection markers and resistance mediating genes are to be categorized if not as genes of medicinal, agronomical or other interest.

Claims 74 and 78 have been amended for clarity.

Claims 96 and 97 have also been amended for clarity.

The examiner rejects claims 90 and 91 as being incomplete. Applicants append hereto a second entry from the Oxford Dictionary of Biotechnology, showing the

definition of gene expression. The entry reads as follows.

> gene expression - the process by which the information carried by a gene or genes becomes manifest as the phenotype. It involves *transcription* of the gene into complementary RNA sequences and, for structural genes, subsequent *translation* of mRNA into polypeptide chains and their assembly into the ultimate protein products.

(p.258.) According to this commonly accepted definition of "gene expression," applicants respectfully submit that one of skill in the art would understand both transcription and translation to take place in the process of the claims at issue.

The examiner rejects claims 92-95 for omitting the step of expression, asserting that transformation of a plant with a construct would not necessarily result in expression of the construct in the transformed plant. Applicants recognize that as a general rule, the examiner is correct. At the same time, the present construct contains a promoter which is activated when plants are under biotic or abiotic stress. Transformation of a plant subjected to such stress with a construct as claimed would, therefore, necessarily result in the expression of the accompanying gene. The step of expression is inherent.

REJECTION UNDER 35 USC §102(B) AND §103(A)

The examiner rejects claims 55-56, 58-63, 65-67, 69, 74, 76, 77, 82, 84-85, and 90 under §102(b) as anticipated by, and claims 55-99 under §103(a) as obvious over, Struve et al. (J.Biol.Chem. 265:14, pp. 7927-7932 (1990)). Applicants reiterate their position that Struve does not disclose a functionally equivalent promoter as such is contemplated by the present invention. Claim to such a functionally equivalent

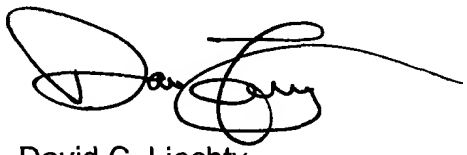
promoter is now set forward in new claim 100. For purposes of furthering the present prosecution, however, applicants have amended claim 55, and respectively submit that the present claims are clearly neither anticipated by nor obvious over Struve et al.

CONCLUSION

In view of the foregoing amendments and remarks, applicants consider that the rejections of record have been obviated and respectfully solicit passage of the application to issue.

Please charge any shortage in fees due in connection with the filing of this paper, including Extension of Time fees to Deposit Account No. 11-0345. Please credit any excess fees to such deposit account.

Respectfully submitted,
KEIL & WEINKAUF



David C. Liechty
Reg. No. 48,692

1350 Connecticut Ave., N.W.
Washington, D.C. 20036
(202)659-0100

DCL/kas

COMPLETE LISTING OF ALL CLAIMS IN THE APPLICATION

1-54 (canceled).

55. (currently amended) A DNA construct comprising the promoter of the *B. vulgaris* ~~plant~~ V-ATPase subunit c in isoform 2 (SEQ ID NO:1) ~~or its functional equivalent~~, operatively linked with a heterologous gene.

56-58 (canceled).

59. (previously added) The DNA construct as claimed in claim 55, which additionally comprises a second promoter which can be regulated in a different manner than the first promoter.

60. (previously added) The DNA construct as claimed in claim 55, which is an expression cassette.

61. (previously added) The DNA construct as claimed in claim 55, wherein the heterologous gene, is a selection marker or a resistance-mediating gene or a gene of other medicinal, agronomical or other interest.

62. (currently amended) A polynucleotide comprising the sequence of the promoter of *B. vulgaris* V-ATPase subunit c isoform 2 set forth in SEQ ID NO: 1 ~~or the functional equivalent of this promoter~~.

63. (previously added) A recombinant vector which additionally comprises the construct as claimed in claim 55.

64. (currently amended) The recombinant vector as claimed in claim 63 ~~64~~, which is a shuttle vector.

65. (currently amended) The recombinant vector as claimed in claim 63 ~~64~~, which is an expression vector.

66. (currently amended) A microorganism which is transformed with the recombinant vector as claimed in claim 63 ~~64~~.

67. (previously added) A transgenic plant cell or transgenic protoplast whose genome encompasses the DNA construct as claimed in claim 55.

68. (currently amended) The transgenic plant cell or transgenic protoplast as claimed in claim 67 ~~68~~ obtained from a monocotyledonous plant.

69. (currently amended) The transgenic plant cell or transgenic protoplast as claimed in claim 67 ~~68~~ obtained from a dicotyledonous plant.

70. (previously added) The transgenic plant whose genome additionally comprises the construct as claimed in claim 55.

71. (currently amended) The transgenic plant as claimed in claim 70 ~~71~~, which is a monocotyledonous plant.

72. (currently amended) The transgenic plant as claimed in claim 70 ~~71~~, which is a dicotyledonous plant.

73. (currently amended) The transgenic plant as claimed in claim 70 ~~71~~, which is sugar beet, tobacco, barley, rice, potato, sunflower, soya, tomato, *Canola*, wheat, oilseed rape, sorghum, carrot, maize, *Mesemranthemum crystallinum* or *Arabidopsis thalinana*.

74. (currently amended) A method for the expression of a heterologous gene, in a

plant cell or a protoplast, which comprises transforming the cell or the protoplast with the DNA construct as claimed in claim 55 and subsequently exposing the transformed cell or the protoplast to a stress that controls the expression of the heterologous gene~~,~~ which has been introduced ~~transformed~~ by means of the DNA construct.

75. (currently amended) The method as claimed in claim 74 ~~75~~, wherein the plant cell or the protoplast is obtained from a monocotyledonous plant.

76. (currently amended) The method as claimed in claim 74 ~~75~~, wherein the plant cell or the protoplast is obtained from a dicotyledonous plant.

77. (currently amended) The method as claimed in claim 74 ~~75~~, wherein the plant cell or the protoplast is obtained from sugar beet, tobacco, barley, rice, potatoes, sunflowers, soya, tomatoes, *Canola*, wheat, oilseed rape, sorghum, carrots, maize, *Mesembranthemum crystallinum* or *Arabidopsis thalinana*.

78. (currently amended) A method for the expression of a heterologous gene in a plant, which comprises regenerating cells or protoplasts transformed with the DNA construct as claimed in claim 55 to produce a transgenic plant and subsequently exposing the plant transformed in this way to a stress that controls the expression of the heterologous gene which has been introduced ~~transformed~~ by means of the DNA construct.

79. (currently amended) The method as claimed in claim 78 ~~79~~, wherein the transgenic plant is a monocotyledonous plant.

80. (currently amended) The method as claimed in claim 78 ~~79~~, wherein the transgenic plant is a dicotyledonous plant.

81. (currently amended) The method as claimed in claim 78 ~~79~~, wherein the transgenic plant is sugar beet, tobacco, barley, rice, potatoes, sunflowers, soya, tomatoes, *Canola*, wheat, oilseed rape, sorghum, carrots, maize, *Mesembranthemum crystallinum* or *Arabidopsis thalinana*.

82. (previously added) A method for producing a recombinant protein, which comprises transforming a plant cell or a protoplast with the DNA construct as claimed in claim 55 and subsequently exposing the transformed cell or the protoplast to a stress which causes the DNA-construct to express the recombinant protein.

83. (currently amended) The method as claimed in claim 82 ~~83~~, wherein the plant cell or the protoplast is obtained from a monocotyledonous plant.

84. (currently amended) The method as claimed in claim 82 ~~83~~, wherein the plant cell or the protoplast is obtained from dicotyledonous plant.

85. (currently amended) The method as claimed in claim 82 ~~83~~, wherein the plant cell or the protoplast is obtained from sugar beet, tobacco, barley, rice, potatoes, sunflowers, soya, tomatoes, *Canola*, wheat, oilseed rape, sorghum, carrots, maize, *Mesembranthemum crystallinum* or *Arabidopsis thalinana.*

86. (previously added) A method of producing a recombinant protein in a plant, which comprises regenerating cells or protoplasts transformed with a DNA construct as

claimed in claim 55 to produce a transgenic plant and subsequently exposing the resulting transgenic plant to a stress which causes the DNA-construct to express the recombinant protein.

87. (currently amended) The method as claimed in ~~din~~ claim 86 ~~87~~, wherein the transgenic plant is a monocotyledonous plant.

88. (currently amended) The method as claimed in claim 86 ~~87~~, wherein the transgenic plant is a dicotyledonous plant.

89. (currently amended) The method as claimed in claim 86 ~~87~~, wherein the transgenic plant is obtained from sugar beet, tobacco, barley, rice, potatoes, sunflowers, soya, tomatoes, *Canola*, wheat, oilseed rape, sorghum, carrots, maize, *Mesembranthemum crystallinum* or *Arabidopsis thalinana*.

90. (previously added) A method of producing a recombinant protein in a plant cell or a protoplast comprising the step of expressing the DNA construct as claimed in claim 55.

91. (previously added) A method of producing a recombinant protein in a plant comprising the step of transforming said plant with the DNA construct as claimed in claim 55.

92. (previously added) A method of expressing a gene in a plant under stress comprising the step of transforming a plant with the DNA construct as claimed in claim 55.

93. (currently amended) A method of expressing a gene in a plant under stress

comprising the step of transforming said plant with the *B. vulgaris* V-ATPase promoter subunit c isoform 2 set forth in SEQ ID NO:1 ~~a plant V-ATPase promoter~~.

94 (canceled).

95. (currently amended) The method as claimed in claim 93 ~~94~~, wherein at least one further pyrimidine stretch is inserted into the promoter.

96. (currently amended) A plant cell or protoplast, which plant cell or protoplast is transformed with the DNA construct as claimed in claim 55 and ~~which~~ is resistant to stress, as a result of the expression of the DNA construct.

97. (currently amended) A ~~The~~ plant cell or protoplast, which plant cell or protoplast is transformed with the DNA construct as claimed in claim 55 and ~~which~~ is resistant to salt stress, as a result of the expression of the DNA construct.

98. (previously added) A plant which is transformed with the DNA construct as claimed in claim 55 and which is resistant to stress, as a result of the expression of the DNA construct.

99. (previously added) The plant which is transformed with a DNA construct as claimed in claim 55 and which is resistant to salt stress, as a result of the expression of the DNA construct.

100. (new) A DNA construct comprising a functional equivalent of the *B. vulgaris* V-ATPase subunit c promoter in isoform 2 (SEQ ID NO:1), operatively linked with a heterologous gene.